K063162

510 (K) Summary
Golden Technologies, Inc.
510 (K) Premarket Notification
Golden Liteway

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

NOV - 2 2006

Golden Technologies, Inc.
401 Bridge Street
Old Forge, Pa. 18518
Phone: (800) 624-6374
Facsimile: (570) 451-7494
Contact Person: Gene Kulon
Official Correspondent
Date Prepared: September 25, 2006

Name of Device and Name / Address of Sponsor:

Golden Liteway

Golden Technologies, Inc.
401 Bridge Street
Old Forge, Pa. 18518
Phone: (800) 624-6374
Facsimile: (570) 451-7494

Common or Usual Name:
3-Wheeled scooter

Classification Name:
Motorized Three-Wheel Vehicle

Comparison to Predicate Devices:

The product, which is substantially equivalent to the Golden Liteway, is the Buzzaround, (K041025). They are both controlled by the use of a paddle type potentiometer, with onboard batteries and battery charger. All safety features are equivalent.

DEVICE DESCRIPTION:
The Golden Liteway is a three wheeled battery powered scooter. It has a 45-amp controller, which is used to operate the Golden Liteway. The one-piece base of the scooter is made of welded steel construction. The drive unit is separable from the floor pan and includes spaced apart, differentially connected rear wheels (2) and an electric motor with a gear housing. It comes standard with a removable

fold down seat, which is connected, to the drive unit frame via a pedestal and seat post concentrating the users' weight near the rear wheels to aid in traction.

All seating meets California Bulletin 117 fire standards. The Golden Liteway comes standard with a compact removable 24-volt battery pack with auto contact and lock and an off board charger. The Golden Liteway has an operating range of 7.5 miles on a full charge at Maximum weight of 300 lbs. The frame can be separated from the rear wheel assembly for stowage and transportation. It has intelligent electronic regenerative braking and a disc parking brake. The weight capacity is 300-lbs and it has a maximum speed of 4-mph.

Intended Use:

The intended use of the Golden Liteway is to provide mobility to persons limited to a seated position that are capable of operating an electric scooter.

Discussion of non-clinical tests performed for determinations of substantial equivalence are as follows:

ANSI/RESNA WC/05 1990 Determination of overall Dimensions, Mass and Turning Space

EN 12184 With Reference to:
EN 55022(B) Emissions
IEC 61000-4-3 Immunity
IEC 61000-4-2 ESD
All EMC tests performed.

ISO 7176-2 (ANSI/RESNA WC/Vol. 2-1998 Section 2) Dynamic Stability Testing
ISO 7176-1 Static stability testing.
ISO 7176-4 Energy Consumption of Electric Wheelchairs and Scooters for determination of theoretical distance range.
ISO 7176-6 Determination of maximum speed, acceleration and deceleration of electric wheelchairs.
ISO 7176-10 Determination of obstacle climbing ability of electric wheelchairs.
ISO 7176-9 2001 Climatic Tests for wheelchair.
ISO 7176-8 (1998) Requirements and test methods for static, impact and fatigue strengths.
TB117 Flammability test (1) SEC. A Part I Flame Retardance Test.

Discussion of Clinical Tests Performed:
N/A

Conclusions:

The Golden Liteway has the same intended use and similar technological characteristics as the Buzzaround. Moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Golden Liteway device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Golden Technologies, Inc.
% Mr. Gene R. Kulon
Official Correspondent
401 Bridge Street
Old Forge, Pennsylvania 18518

NOV - 2 2006

Re: K063162
Trade/Device Name: Golden Liteway, Vehicle, Motorized 3-Wheeled
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: Class II
Product Code: INI
Dated: September 15, 2006
Received: October 18, 2006

Dear Mr. Kulon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K-063162

Device Name: Golden Liteway, Vehicle, Motorized 3-Wheeled

Indications for Use:

The intended use of the Golden Liteway is to provide a lightweight scooter that offers mobility to persons limited to a seated position who are capable of operating a simple hand control.

Prescription Use _X_ (Per 21 CFR 801Subpart D) AND/OR Over-The-Counter Use _X_ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) N